

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

DATE MAILED: 06/27/2002

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|---------------------|------------------|
| 09/489,982 | 01/21/2000 | Thomas G Stoll | 99,308 | 6538 |
| 7: | 590 06/27/2002 | | | |
| SHUGHART, THOMSON & KILROY, P.C. Twelve Wyandotte Plaza 120 West 12th Street | | | EXAMINER | |
| | | | BLECK, CAROLYN M | |
| Kansas City, MO 64105 | | | ART UNIT | PAPER NUMBER |
| | | | 3626 | |
| SHUGHART, THOMSON & KILROY, P.C. Twelve Wyandotte Plaza | | | BLECK, CA | ROLYN M |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|--|---|--|--|--|
| | 09/489,982 | STOLL ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| • | Carolyn M Bleck | 3626 | | | |
| The MAILING DATE of this communication appeared for Reply | ears on the cover sheet with the c | correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 6(a). In no event, however, may a reply be tir within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| 1) Responsive to communication(s) filed on 21 J | anuary 2000 . | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ Thi | s action is non-final. | | | | |
| 3) Since this application is in condition for allowa | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | |
| 4) Claim(s) 1-19 is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>1-19</u> is/are rejected. | | | | | |
| 7)⊠ Claim(s) <u>1-4,6-9,12,13,15,16 and 18</u> is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) All b) Some * c) None of: | t to the second second | | | | |
| 1. Certified copies of the priority documents | | ian Na | | | |
| 2. Certified copies of the priority documents | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14)☐ Acknowledgment is made of a claim for domestic | c priority under 35 U.S.C. § 119(| e) (to a provisional application). | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |
| J.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office Ac | tion Summary | Part of Paper No. 4 | | | |

Art Unit: 3626

DETAILED ACTION

Notice to Applicant

This communication is in response to the application filed 21 January 2000.
 Claims 1-19 are pending. The IDS statement filed 21 January 2000 has been entered and considered.

Claim Objections

- 2. Claims 1-4, 6-9, and 12-13 are objected to because of the following informalities: line 2 of claims 1 and 7 and line 1 of claims 2-6, 8-9, and 12-13, it appears the phrase "A method... and including the steps(s)..." is grammatically incorrect. The word, "and," could be removed from the preamble in order to be grammatically correct. Appropriate correction is requested.
- 3. Claims 15-16 and 18 are objected to because of the following informalities: line 1 of claims 15-16 and 18, it appears the phrase "An apparatus... and including..." is grammatically incorrect. The word, "and," could be removed from the preamble in order to be grammatically correct. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3626

5. Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claims 15-19, line 1, "An apparatus" lacks proper antecedent basis as claims 15-19 refers to an apparatus and claim 14 refers to a digital prescription carrier apparatus. For purposes of applying prior art, "an apparatus" of claims 15-19 is being interpreted as a digital prescription carrier apparatus.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz (6,397,190).
- (A) As per claim 1, Goetz discloses a method for managing prescribed medications comprising:
- (a) providing an electronic component (reads on "digital prescription carrier") capable of scheduling and tracking a number of different prescriptions and administration frequencies, wherein the electronic component includes read/write memory and a communication interface (Fig. 1, col. 2 lines 16-25, col. 4 lines 15-45, col.

Art Unit: 3626

5 lines 47-52, col. 6 lines 44-52, col. 9 line 19 to col. 10 line 14, col. 17 lines 20-35, and col. 18 lines 19-38);

- (b) transferring prescription information into the electronic component through the communication interface, wherein the prescription information includes medication name and purpose, dosage, frequency, duration, and any special considerations in consuming the medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);
- (c) bringing an electronic component by a handler/owner (reads on "patient") to a pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);
- (d) importing prescription information from an electronic component through a communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48); and
- (e) filling a prescription at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48).

Goetz fails to expressly disclose using the method for managing prescribed medications in a traditional medical environment. It is noted that the Goetz method is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's method in a traditional medical environment with the motivation of ensuring patients are taking medications are correctly, minimizing the number of errors

Art Unit: 3626

in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

- (B) As per claim 2, Goetz discloses entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24).
- (C) As per claim 3, Goetz discloses a method for managing prescribed medications including:
- (a) operating a scheduling and alarm function for prescribed treatments or medications within an electronic component to generate internal values of date and time (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22);
- (b) providing an electronic component with an input button interfaced to an alarm (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22);
- (c) pressing an input button to accept or acknowledge administering a prescription (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22); and

Art Unit: 3626

- (d) logging in memory the time/date when the prescribed medication is administered (Fig. 7, col. 2 lines 5-15, col. 4 lines 15-26, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22).
- (C) As per claim 4, Goetz discloses a method for managing prescribed medications including:
- (a) providing an electronic component with an alarm, wherein the alarm is audible, visual, or tactile such as a vibrator device (col. 5 lines 25-45);
- (b) inputting into an electronic component by a pharmacist, prescription information defining the desired medication, total dosage, and a schedule for administering each medication including the date and time (col. 11 line 24 to col. 12 line 16 and col. 13 lines 40-67);
- (c) comparing the current time and date to the time and date tag for each active prescription stored in the electronic component (col. 13 lines 40-67); and
- (d) generating an alarm when a dose of a prescription has time and date tags equal to or less than the current time and date (col. 13 lines 40-67).
- (D) As per claim 5, Goetz discloses providing an electronic component with an infrared communication interface (col. 9 lines 19-49 and col. 18 lines 55-58).
- (E) As per claim 6, Goetz discloses a method for managing prescribed medications including:

Application/Control Number: 09/489,982 Page 7

Art Unit: 3626

(a) uploading prescribed medication data for one or more medications into an electronic component through a communication interface by a veterinarian or health care specialist (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10 lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);

- (b) downloading prescribed medication data through a communication interface (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4); and
- (c) filling one or more prescriptions defined by prescribed medication data (col. 6 lines 2-14 and col. 10 lines 30-48).
- (F) Claims 7-9 and 11-13 repeat the same limitations of claims 1-6, and are therefore rejected for the same reasons given for those claims.
- (G) As per claim 10, Goetz discloses an electronic component with an alarm, wherein the alarm is a vibrator device (col. 5 lines 25-45 and col. 8 lines 23-53).
- (H) As per claim 14, Goetz discloses an electronic component for storing prescription data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col. 21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:
 - (a) a housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14);

Art Unit: 3626

(b) a central processing unit enclosed within the housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14);

- (c) an LCD screen included in the housing and interfaced with the CPU, and capable of displaying alphanumeric characters (Fig. 25-43, col. 5 lines 5-10, and col. 9 line 50 to col. 10 line 14);
- (d) electronic circuitry enclosed in the housing and interfaced to the CPU, wherein the electronic circuitry interfaces the CPU to an external personal computer (Fig. 25-43, col. 5 lines 5-10, and col. 9 line 19 to col. 10 line 14);
- (e) memory enclosed in the housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line14); and
- (f) prescription software stored in memory to be processed by the CPU (col. 7 lines 25-38 and col. 12 line 31) to enable uploading prescribed medication data for one or more medications into memory through a communication interface by a veterinarian (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10 lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4) and downloading prescribed medication data through a communication interface at a clinic pharmacy (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4).

Goetz fails to expressly disclose using a digital prescription carrier apparatus for managing prescribed medications in a traditional medical environment. It is noted that the Goetz system is used in a veterinary medical environment. It is respectfully

Art Unit: 3626

submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's system in a traditional medical environment with the motivation of ensuring patients are taking medications correctly, minimizing the number of errors in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

- (I) Claims 15-16 repeat the same limitations as claims 3-4 and 14, and are therefore rejected for the same reasons given for those claims.
- (J) As per claim 17, Goetz discloses an alarm device, wherein the alert device is an audible alarm interfaced to a CPU or a vibrating device interfaced to a CPU (col. 4 lines 37-67 and col. 5 lines 5-36).
- (K) As per claim 18, Goetz discloses an electronic component for storing prescription data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col. 21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:
- (a) a set of button controls positioned on the housing and interfaced to the CPU(Fig. 25-43 and col. 9 line 50 to col. 10 line 14);
- (b) prescription software causing transferred prescription data to generate a schedule of dose times for a medication represented by prescription data (Fig. 8A and 8B and 25-43, col. 9 line 50 to col. 10 line 14, col. 10 lines 30-48, and col. 13 lines 40-53); and

Application/Control Number: 09/489,982 Page 10

Art Unit: 3626

(c) operation of button controls enabling a review of scheduled dose times for a medication, wherein the schedule is displayed on an LCD device (Fig. 8A and 8B and 25-43, col. 9 line 50 to col. 10 line 14, and col. 10 lines 30-48, and col. 13 lines 40-53).

(L) Claim 19 repeats the same limitations as claim 5, and is therefore rejected for the same reasons given for claim 5.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a system and method for ordering and prescribing drugs for a patient including electronic pen-based entry (5,758,095), an electronic prescription creation system for use by prescribers at the point of care (5,737,539), a wirelessly deployable, electronic prescription creation system for physician use (5,845,255), a prescription compliance device to aid patients in complying with instructions given by a physician (6,018,289), a medical reminder system including an electronic messaging watch which is programmed with a medication regimen for a patient (6,075,755), a system and method for providing self-management of medication treatment by patients (6,294,999), a portable system for reminding a patient and keeping track of prescriptions and the use of medications (6,314,384), and an interactive reminder device (6,335,907).

Page 11

Application/Control Number: 09/489,982

Art Unit: 3626

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The examiner can normally be reached on Monday-Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

10. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks Washington, D.C. 20231

Or faxed to:

(703) 305-7687 [Official communications; including After Final

communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled

"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

Art Unit: 3626

June 18, 2002

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3600